

What is claimed is:

1. A method of continuously analyzing trial data of an ongoing clinical trial, the method comprising:
  - accessing a trial database containing trial data of subjects in a clinical trial;
  - performing a statistical analysis on the accessed trial database;
  - determining whether the result of the statistical analysis exceeds a predetermined threshold value; and
  - if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, then repeating the steps of accessing, performing and determining while the clinical trial is ongoing.
2. The method according to claim 1, prior to the step of performing a statistical analysis, further comprising:
  - reading a user defined criteria that defines the level of cleanliness of the trial data for statistical analysis; and
  - retrieving only those trial data that meet the user defined criteria from the trial database.
3. The method according to claim 1, wherein if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, then waiting for a predetermined time period prior to the repeating step.
4. The method according to claim 1, wherein the clinical trial is a blinded clinical trial, further comprising:
  - accessing a blinding database containing subject identifiers and associated study group identifiers, each study group identifier identifying to which study group an associated subject belongs; and
  - producing a grouped database from the clinical database and the blinding database for statistical analysis, the grouped database grouping the study data according to the study group.
5. The method according to claim 4, wherein the grouped database is stored in a memory device that is inaccessible by any user.

6. The method according to claim 1, wherein the step of performing a statistical analysis is executed without locking the trial database.
7. The method according to claim 1, wherein the clinical trial is a blinded clinical trial, further comprising:
  - reading a predefined criteria that defines the level of cleanliness of trial data required for analysis;
  - retrieving only those trial data that meet the predefined criteria from the trial database;
  - accessing a blinding database containing subject identifiers and an associated study group identifier for each subject, each study group identifier identifying to which study group each subject belongs; and
  - producing a grouped database from the retrieved trial data and the blinding database for statistical analysis, the grouped database grouping the trial data according to the study group.
8. The method according to claim 7, wherein the grouped database is stored in a memory device that is inaccessible by any user to preserve the blindness of the clinical trial.
9. The method according to claim 1, further comprising alerting a user if it is determined that the result of the statistical analysis exceeds the predetermined threshold value.
10. The method according to claim 9, wherein the predetermined threshold value includes a predetermined statistical significance value.
11. The method according to claim 10, wherein the step of performing a statistical analysis comprises:
  - retrieving a user defined statistical model; and
  - running the retrieved user defined statistical model on the trial database.
12. A method of continuously analyzing trial data of an ongoing blinded clinical trial, the method comprising:
  - accessing a trial database containing blinded trial data of subjects in an ongoing blinded clinical trial;

accessing a blinding database containing subject identifiers and associated study group identifiers, each study group identifier identifying to which study group an associated subject belongs;

producing a grouped database from the trial database and the blinding database, the grouped database grouping the trial data according to the study group;

performing a statistical analysis on the produced grouped database;

determining whether the result of the statistical analysis exceeds a predetermined threshold value; and

if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, then repeating the above steps of:

accessing a trial database,

producing a grouped database,

performing a statistical analysis, and

determining

while the clinical trial is ongoing.

13. The method according to claim 12, prior to the step of performing a statistical analysis, further comprising:

reading a user defined criteria that defines the level of cleanliness of trial data for statistical analysis; and

retrieving only those trial data that meet the user defined criteria from the trial database for statistical analysis.

14. The method according to claim 12, wherein the produced grouped database is stored in a memory device that is inaccessible by any user.

15. The method according to claim 12, wherein the step of performing a statistical analysis is executed without locking the trial database.

16. The method according to claim 12, further comprising alerting a user if it is determined that the result of the statistical analysis exceeds the predetermined threshold value.

17. The method according to claim 16, wherein the predetermined threshold value includes a predetermined statistical significance value.

18. A system for continuously analyzing an ongoing clinical trial comprising:  
a storage device operable to store a trial database containing trial data of subjects in an ongoing clinical trial;  
a processor coupled to the storage device; and  
an analysis program executable by the processor and operable to:  
perform a statistical analysis on the trial database;  
determine whether the output result of the statistical analysis exceeds a predetermined threshold value; and  
repeat the statistical analysis while the clinical trial is ongoing if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value.
19. The system according to claim 18, wherein the analysis program is further operable to:  
read a user defined criteria that defines the level of cleanliness of trial data for statistical analysis; and  
retrieve only those trial data that meet the user defined criteria from the trial database.
20. The system according to claim 18, wherein if the analysis program determines that the result of the statistical analysis does not exceed the predetermined threshold value, then the analysis program waits for a predetermined time period prior to repeating the statistical analysis.
21. The system according to claim 18, wherein the clinical trial is a blinded clinical trial, the analysis program further operable to:  
access a blinding database containing subject identifiers and associated study group identifiers, each study group identifier identifying to which study group an associated subject belongs; and  
produce a grouped database from the trial database and the blinding database for statistical analysis, the grouped database grouping the trial data according to the study group.
22. The system according to claim 21, further comprising a memory device coupled to the processor and being inaccessible to any user, wherein the grouped database is stored only in the memory device.

23. The system according to claim 18, wherein the analysis program performs the statistical analysis without locking the trial database.

24. The system according to claim 18, wherein the analysis program is further operable to alert a user if it determines that the result of the statistical analysis exceeds the predetermined threshold value.